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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|----------------------------------------------------------------------------|-------------|-----------------------------|---------------------|------------------|
| 10/550,681 | 09/26/2005 | Jerachmiel (Yori) Appelbaum | 30667 | 8344 |
| 67801 13/06/2008 MARTIN D. MOYNIHAN d/b/a PRTSI, INC. P.O. BOX 16446 | | | EXAMINER | |
| | | | PACKARD, BENJAMIN J | |
| ARLINGTON, VA 22215 | | | ART UNIT | PAPER NUMBER |
| | | | 1612 | |
| | | | | |
| | | | MAIL DATE | DELIVERY MODE |
| | | | 11/06/2008 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

| Application No. | Applicant(s) | | |
|------------------|---------------------------------|--|--|
| 10/550,681 | APPELBAUM, JERACHMIEL (YORI) | | |
| Examiner | Art Unit | | |
| Benjamin Packard | 1612 | | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

| Period for Reply |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 3T GPT, 175(ii). In no event, however, may a neply be timely filed - If NO prince for reply is specified above, the maximum statutory period will apply and will expres SN (0) MONTHS from the mailing date of this communication Failure to reply within the set or extended period for reply will, by stated, cause the application to become MARMONNED (35 US.C.§ 133). Any reply received by the Office later than three months after the making date of this communication, even if timely filed, may reduce any earned patter term adjustment. See 3T GPTR (170(b)). |
| Status |
| Responsive to communication(s) filed on 29 July 2008. 2a) ☐ This action is FINAL. 2b ☐ This action is non-final. 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is |
| closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. |
| Disposition of Claims |
| 4) Claim(s) 1-18.20.22-24 and 26-32 is/are pending in the application. 4a) Of the above claim(s) 1-18 and 26-32 is/are withdrawn from consideration. 5) Claim(s) is/are allowed. 6) Claim(s) 20 and 22-24 is/are rejected. 7) Claim(s) is/are objected to. 8) Claim(s) are subject to restriction and/or election requirement. |
| Application Papers |
| 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are: a) considered or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. |
| Priority under 35 U.S.C. § 119 |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some comment of the priority documents have been received. Certified copies of the priority documents have been received in Application No Copies of the certified copies of the priority documents have been received in Application No The copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). See the attached detailed Office action for a list of the certified copies not received. |

Attachment(s)

1) Notice of References Cited (PTO-892) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 Information Disclosure Statement(s) (PTO/SB/08)

Paper No(s)/Mail Date 2pgs(06/26/2008).

| | Interview Summary (PTO-413) Paper No(s)/Mail Date. |
|----|----------------------------------------------------|
| 5) | Notice of Informal Patent Application |
| 6) | Other: |

Part of Paper No./Mail Date 20081029

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DETAILED ACTION

Applicants' arguments, filed 07/29/2008, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Election/Restrictions

Per Applicants request, Examiner notes that claims 26-33 were withdrawn as being directed to non-elected species, not due to the withdrawal of the non-elected invention of Group I.

Claim Rejections - 35 USC § 102

Claims 20, 22, and 23 were rejected and amended claim 24 is now rejected under 35 U.S.C. 102(b) as being anticipated by Fernidandy et al (PTO-892 dated 11/02/2007, item U).

This rejection is maintained.

Applicants assert they amended around ischemic heart injury and that the various teaching of the reference are different than the instant claims.

In response, Examiner points out that amended claim 20 still includes the treatment of ischemic heart disease. Therefore, the treatment as discussed in the prior application still anticipates the instant claims where ischemic heart injury can be construed as an ischemic heart disease.

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Further, it is noted that the method of treatment of claims 20 and 22-24 simply requires the administration of TPEN for the conditions instantly claimed in claim 20, which appear to be pathological conditions influenced by the action of MMP. Where the limitations of instant claim 20 are met, it would appear that the mechanisms of claims 22-24 reasonably expected to be inherent. The discovery of a new mechanism does not overcome the anticipation rejection for the method of treatment.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 20, 22, and 23 were rejected and amended claim 24 is now rejected are rejected under 35 U.S.C. 102(e) as being anticipated by Fernandez-Pol et al. (US

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Pregrant Publication 2003/0225155, now US 6803379, filed 6/4/2002, published 12/4/2003).

Applicants assert Fernandez-Pol et al teaches away from the instant claims. Examiner again notes that the method of treatment of claims 20 and 22-24 simply requires the administration of TPEN for the conditions instantly claimed in claim 20, which appear to be pathological conditions influenced by the action of MMP. Where the limitations of instant claim 20 are met, it would appear that the mechanisms of claims 22-24 reasonably expected to be inherent. Even if the teaching of the prior art does not appear to be similar to the present application; the discovery of a new mechanism does not overcome the anticipation rejection for the method of treatment where the same drug is administered for the same disease.

Conclusion

No claims allowed.

Applicant's amendment necessitated the new ground(s) of rejection for claim 24 presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Benjamin Packard whose telephone number is 571-270-3440. The examiner can normally be reached on M-R 8-5 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Benjamin Packard/ Examiner, Art Unit 1612 Application/Control Number: 10/550,681

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Supervisory Patent Examiner, Art Unit 1612